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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,080	07/21/2003	Ganjam V. Kalpana	96700/819	5994

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AMSTER, ROTHSTEIN & EBENSTEIN LLP
90 PARK AVENUE
NEW YORK, NY 10016

EXAMINER

HORNING, MICHELLE S

ART UNIT	PAPER NUMBER
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1648

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/624,080

Applicant(s)

KALPANA, GANJAM V.

Examiner

Michelle Horning

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/21/2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-17,24,25 and 31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-17, 24-25, 3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is responsive to communication filed 11/21/2006. The status of the claims is as follows: claims 1, 3-17, 24-25 and 31 are under current examination and claims 2, 18-23, 26-30 and 32-90 have been cancelled.

Objection to the Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejection Withdrawn

The rejection of claims 14, 19, 24 and 31 under 35 U.S.C. 112, 2nd paragraph has been withdrawn in view of the claim amendments.

Claim Rejections

35 U.S.C. 101-MAINTAINED

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 and 5-16 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. As stated in the previous office action, these claims are drawn to a production of nature (i.e. all peptides in nature "comprising an Rpt1 domain of an Inl1/hSNF5 or a cell comprising the peptide). The

previous office action suggested identifying the peptide as either "isolated" or "purified" in order to eliminate this rejection.

Further, regarding this rejection, the previous office action points out that results from US Patent 5, 872, 213 "suggest that the ini-1 gene is very widely, and possibly ubiquitously, expressed" as determined by isolating INI-1 RNA from a number of tissues (col. 9, under Expression of the Ini-1 mRNA in mammalian cells); thus, this suggests that nearly all cells comprise this peptide. The actual cells were also addressed under this rejection in that the claims (claims 10-16) do not distinctly claim a cell in isolated form and may encompass all existing cells, including those cells found in nature.

RESPONSE TO ARGUMENTS

In response to the above rejection, Applicants have amended claim 1 to further specify that "the peptide is a fragment of Inl1/hSNF5" which does not occur in nature and thus, as suggested by Applicant, this rejection should be withdrawn. However, the specification does not provide a definition of "fragment" and peptide fragments do occur in nature. Given that peptides do degrade or undergo enzymatic cleavage in nature, resulting in peptide fragments, the amendment of claim 1 is still directed to a product of nature. Thus, this rejection is maintained.

35 U.S.C. 102-MAINTAINED

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-7, 9-17, 24-25 and 31 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by US Patent 5, 872, 213. As stated in the previous office action (excluding claim 31), all of the limitations of the above claims are taught by US Patent 5, 872, 213, including the following: 1. a peptide comprising SEQ ID NO: 2, 3 or 5; 2. the peptide is in human cells, including T cell and hematopoietic stem cell; 3. the peptide does or does not comprise a non-peptide moiety; 4. the peptide is present in sufficient amount to inhibit replication or virion production in the cell, or the spread of HIV-1 to another cell; 5. a cell expressing the peptide; 6. a vector encoding SEQ ID NO: 2 without any non-peptide moiety; 7. a vector encoding SEQ ID NO: 2 without any non-peptide moiety is expressed in a human cell; and 8. a vector encoding SEQ ID NO: 2 without any non-peptide moiety is expressed in a human cell in amount sufficient to inhibit replication or virion production of HIV-1 in the cell. Of note, claim 31 previously depended on a cancelled claim and was amended to depend on claim 25.

RESPONSE TO ARGUMENTS

Applicant traversed this rejection for the following reasons: US Patent 5, 872, 213 does not disclose: 1. a peptide that comprises an Rpt1 domain that inhibits HIV-1 production; 2. a peptide that is a fragment of INI1/hSNF5; 3. a fragment of the full length INI-1 that inhibits HIV-1 virion production; and 4. that SEQ ID NO: 2, 3 or 5 is inhibitory

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to HIV-1 virion production. All of the above assertions are incorrect and are addressed below.

While US Patent 5, 872, 213 does not expressly use the term "Rpt1 domain" or "INI1/hSNF5" as dubbed by the instant application, the sequences of the instant application are homologous to the peptides set forth in SEQ ID NO: 3 and other sequences throughout the patent. This patent also teaches the following: "Finally, the identification of a host protein as interacting with the HIV-1 IN raises the possibility that it may be used as a novel route to inhibit viral replication. If the protein serves to stimulate integration, then drugs which could block the interaction might retard viral spread. In addition, it might be possible to generate dominant negative alleles of ini-1 , perhaps encoding small fragments of the protein, that bind inappropriately to IN and block its activity." (col. 13). Thus, this patent does disclose a sequence dubbed as the Rpt1 or INI-1/hSNF5 is peptide inhibits viral replication.

In US Patent 5, 872, 213, the peptides set forth in SEQ ID NOs: 3 and 4 are fragments of SEQ ID NO: 2 (full length INI-1). The abstract of this patent clearly states that the full length INI-1 binds tightly to the HIV-1 integrase and that the "INI-1 gene product will prove useful for the generation of biochemical reagents and the development [of] novel HIV-1 antiviral agents" (see Abstract).

Lastly, the Applicants argue that this patent does not teach that SEQ ID NO: 2, 3 or 5 is inhibitory to HIV-1 virion production. While this is true regarding peptides that consists of the sequence set forth in SEQ ID NO: 2 and 3 (and not SEQ ID NO: 5 for reasons discussed above), the Office would like to respectfully remind the Applicants that the claims use the "comprising" word or its verb variants (except for claim 8). Thus, as a single example, this patent teaches SEQ ID NO: 3 which comprises both SEQ ID NO: 2 and 3 of the instant application.

For the reasons above, this rejection is maintained.

CONCLUSION

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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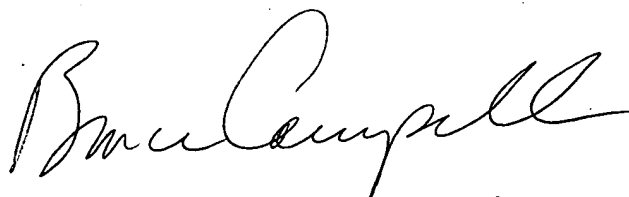
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle Horning whose telephone number is 571-272-9036. The examiner can normally be reached on Monday-Friday, 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campbell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 570-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for unpublished application is available through Private PAIR only. For more information about PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michelle Horning
Patent Examiner



BRUCE R. CAMPBELL, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600